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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/083,590 06/25/93 ARTAVANIS-TSAKONAS

S 7306015
EXAMINER

SCHEINER, T

ART UNIT	PAPER NUMBER
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NEW YORK, NY 10036-2711

18N1/1214

1802

DATE MAILED:

12/14/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8/15/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.  | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.                  |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-89 are pending in the application.  
Of the above, claims 1-68 and 75-89 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 68-74 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's election with traverse of Group IX, claims 68-74 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that "[t]he individual groups of claims specified by the Examiner are not distinct inventions, but rather an intricate web of knowledge and continuity of effort which merit examination of all claims in a single application" and "[e]ven assuming *arguendo* that Groups I-IX represented distinct or independent inventions, applicants submit that to search the subject matter of all the Groups together would not be a serious burden on the Examiner." This has not been found persuasive because the various groups encompass chemically distinct products made by and used in different methods, as well as several methods which use products and steps not used in the other methods; because each of these Groups includes products and method steps not found in the other Groups, there is little or no overlap in the searches for the various Groups and therefore, searching the subject matter of all the Groups together would indeed be a serious burden.

~~together would indeed be a serious burden.~~

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The requirement is still deemed to be proper and is therefore made FINAL.

Claims 1-89 are pending in the application, but claims 1-67 and 75-89 are withdrawn from consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 68-74 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to methods of screening for the

presence of malignancies and "nervous system disorders" by measuring the expression of Notch protein (actually, in a patient, this should be referred to as *ZN-1*, the designation for the human homolog) and comparing the level of expression with normal levels.

The specification indicates that aberrant (increased or decreased) expression or activity of Notch protein is associated with several dozen conditions. In light of this, confirmation of aberrant expression or aberrant activity of Notch protein alone cannot be used to definitively diagnose or distinguish any particular condition. Similarly, there is no indication that aberrant Notch protein expression or activity is found in virtually all of these particular disorders. Because of this, the instant method is considered to be a method of screening for disorders, rather than a method of diagnosis. Moreover, the specification is enabling only for claims limited to methods of screening for malignancies or "nervous system disorders." While the specification mentions many examples of each of these broad categories of disorders, no guidance is provided for other conditions which may be associated with aberrant expression or activity of Notch protein. In the absence of further guidance, it would require an undue amount of experimentation for one of ordinary skill in the art to determine whether a condition other than a malignancy or a "nervous system disorder" was present in an individual exhibiting aberrant expression of Notch protein. Finally, the specification is enabling only for measuring aberrant Notch protein expression, as opposed to aberrant activity, in a patient. The specification does not define Notch protein "activity," nor does it indicate that the exact function or mechanism of action of the *ZN-1* protein is known. In the absence of any guidance for measuring some parameter of activity or function, it would require an undue amount of experimentation for one of ordinary skill in the art to determine whether or not aberrant Notch protein activity was present in a sample. See MPEP 706.03(n) and 706.03(z).

Serial No. 08/083590  
Art Unit 1802

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Toni R. Scheiner whose telephone number is (703) 308-3983. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0396.

TRS  
11/14/94

*Toni R. Scheiner*

TONI R. SCHEINER  
PRIMARY EXAMINER  
GROUP 1800